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AKZO NOBEL

(302) 934-4340

17 December 2004

Dr. Lonnie Luther, Staff Chief (HFV-102)
C/O: Dockets Management Branch, HFA-305
Room 1061
5630 Fishers Lane
Food and Drug Administration
Rockville, MD 20852

RE: SUITABILITY PETITION FOR REVIEW AND ACTION – Omeprazole Tablet for Horses (JINAD 11-165)

Dear Dr. Luther:

Please find enclosed a suitability petition for Agency review and action. Intervet Inc. is requesting permission to file an abbreviated new animal drug application (ANADA) for a generic omeprazole tablet that differs in dosage form from the pioneer product (UlcerGard™, NADA 141-227).

Your timely review of the enclosed petition will be greatly appreciated.

Please feel free to call (302-934-4340) or e-mail (mary.hagler@intervet.com) me should you have any questions or if I can be of assistance.

Sincerely,

Mary K. Hagler

Mary K.Hagler, MS
Senior Regulatory Affairs Specialist – Pharmaceuticals
Intervet Inc.

Enclosure

intervet

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29160 Intervet Lane

Intervet Inc
~~405 State Street~~
PO Box 318
Millsboro DE 19966-0318
Tel (302) 934-8051
FAX (302) 934-4292

Suitability Petition

Intervet Inc.
Omeprazole Tablet for Horses
17 December 2004

The undersigned submits this petition under Section 512 (n) (3) of the Federal Food, Drug, and Cosmetic Act to request the Commissioner of Food and Drugs to permit the filing of an abbreviated new animal drug application for a generic oral omeprazole formulation that differs from the reference product (UlcerGard™ (omeprazole) NADA 141-227) in dosage form and strength of the active ingredient in the proposed drug product.

Action Requested

We are requesting that the Commissioner permit the filing of an abbreviated new animal drug application for our proposed palatable omeprazole tablet for horses (trade name to be determined). The abbreviated application will include bioequivalence and consumption studies. Our proposed product differs from the reference product as follows:

Reference Product

Trade name

UlcerGard™ (NADA 141-227)

Active ingredients

Omeprazole

Dosage form

Paste for oral administration

Strength

37% w/w omeprazole (570 mg omeprazole per dose)

Sponsor

Merial Limited.

Directions for Use

Each syringe contains 4 individual daily doses for horses weighing 600-1200 lbs. Please refer to the following dosage chart for help in determining the correct dose for your horse.

Horse Weight	Dose
< 600 lbs	Consult a veterinarian
600-1200 lbs	1 dose per day
over 1200 lbs	2 doses per day

Proposed Drug Product

Trade name

To be selected

Active ingredients

Omeprazole

Dosage form

Palatable tablet

Strength

19% w/w omeprazole (570 mg omeprazole per tablet)

Sponsor

Intervet Inc.

Directions For Use

Each tablet is a daily dose for a horse weighing 600-1200 lbs. Please refer to the following dosage chart for help in determining the correct dose for your horse.

Horse Weight	Dose
< 600 lbs	Consult a veterinarian
600-1200 lbs	1 tablet per day
over 1200 lbs	2 tablets per day

Each package contains enough palatable tablets to treat a 600-1200 lbs horse for 28 days.

Statement of Grounds

A palatable dosage form has been selected for the proposed drug product to increase the likelihood that the horse owner will be successful in administering the required amount of omeprazole to prevent gastric ulcers in horses. The currently available omeprazole paste requires the horse-owner to restrain the horse and force the applicator into the horse's mouth to administer the dose.

After the dose is administered, the horse may still reject all or part of the dose by spitting it out. This can result in administering the wrong dose to the horse if the rejection is not observed or if excess paste is administered due to inaccurate estimation of the amount of paste rejected. To obviate these problems we propose to formulate omeprazole in a palatable dosage form that could be offered to the horse and be readily accepted. In this manner the horse owner can be assured that the horse received the complete dose of omeprazole.

The change in strength of the active ingredient is necessitated by the change in dosage form. However, the dose administered per pound body weight and the body weight intervals used to determine the amount of drug product administered would remain the same as the reference product. This would result in a horse of any weight receiving the same amount of omeprazole as in the reference product.

Environmental Impact

Intervet Inc. requests a categorical exclusion from the requirements to file an environmental impact assessment under 21 CFR 25.33 (d) (1) as the drug is intended for use in nonfood animals.

Economic Impact

Information pertaining to the economic impact of this petition will be submitted if requested by the commissioner.

Certification

Intervet Inc. certifies that this suitability petition contains all information known to them that is unfavorable to the petition.

Carl K. Johnson, AM, DVM
Director, Pharmaceutical Product Development
and Regulatory Affairs

17 Dec 04
Date